Duquesne Law Review

Volume 13 | Number 4 Article 9

1975

Experimentation on Minors: Whatever Happened to Prince v. Massachusetts

Annina M. Mitchell

Experimentation on Minors: Whatever Happened to *Prince v. Massachusetts*?

*Annina M. Mitchell**

> [I]n eighteenth century England . . . Caroline, Princess of Wales, "begged the lives" of six condemned criminals for experimental smallpox vaccination before submitting her own children to the procedure. (She also procured, for further trial, "half a dozen of the charity children belonging to St. James' parish.")[1]

Our system of "volunteering" children as experimental subjects has not changed very much since the days of Caroline, Princess of Wales. Although the field of medical research has become much more sophisticated and institutionalized, our methods of selecting children as subjects remain the same, which is to say that there are no established methods of selection. Parents and legal guardians (often including institutional custodians) continue to exercise their own individual judgment as to whether or not minors under their control will be used as research subjects, despite the fact that their legal authority to do so has never been clearly established.[2]

Although a few commentators have considered the issue of the use of minors in clinical investigation,[3] the starting point for their discussion has been an assumption that there is a need for human experimentation on children if medical knowledge is to expand and progress. This assumption, while undoubtedly true, glosses over the

---

* Law clerk to Justice Swenson, Michigan Supreme Court.

1. Lasagna, *Special Subjects in Human Experimentation*, 98 DAEDALUS 449 (1969).

2. The guardian's "right" to give third party consent on behalf of a minor for purposes of experimentation is usually justified as an extension of the right to consent to normal medical treatment. *See* text accompanying notes 31-37 *infra*.

3. *See, e.g.*, H. BEECHER, RESEARCH AND THE INDIVIDUAL 63-69 (1970); Capron, *Legal Considerations Affecting Clinical Pharmacological Studies in Children*, 21 CLINICAL RESEARCH 141 (1973); Curran & Beecher, *Experimentation in Children*, 210 J.A.M.A. 77 (1969); Fletcher, *Human Experimentation: Ethics in the Consent Situation*, 32 LAW & CONTEMP. PROB. 620 (1967) [hereinafter cited as Fletcher]; Lasagna, *Special Subjects in Human Experimentation*, 98 DAEDALUS 449 (1969); Lowe, Alexander & Mishkin, *Nontherapeutic Research on Children: An Ethical Dilemma*, 84 J. PED. 468 (1974); Marston, *Research on Minors, Prisoners and the Mentally Ill*, 288 NEW ENG. J. MED. 158 (1973); Note, *Experimentation on Human Beings*, 20 STAN. L. REV. 99 (1967). *See generally* J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS (1972); M. PAPPWORTH, HUMAN GUINEA PIGS (1967).

underlying issue of whether we should be committed to the goal of medical progress at any price. More and more frequently, the answer is becoming a reluctant "no." In regard to all special subjects of human experimentation—prisoners, children and mental patients—there is an increasing awareness that some regrettable, but necessary, limits must be placed on medical progress through experimentation. It is now becoming recognized that, in certain instances, the costs—in terms of personal integrity and autonomy—may otherwise be too dear.[4]

The problems raised by non-therapeutic research (experimentation) on minors have recently been characterized as presenting a two-fold dilemma: first, the legal question of whether parents and guardians have legal authority to consent to the inclusion of minors in experimentation; secondly, the ethical question of whether, and under what conditions they should consent, even given legal authority to do so.[5] These matters raise difficult questions which, heretofore, have been politely discussed and then shoved under the table by medical, legal and ethical writers and practitioners. Even though there has been a rapid expansion of clinical research as a branch of medicine in the last fifty years,[6] the law has lagged far behind in the entire area of human experimentation.[7] Sparse literature on human

4. The issue is clear; if children cannot participate in research, we can make little progress toward the goal of improved diagnosis, prevention, treatment, or understanding of children's diseases. But the establishment of need is not sufficient; the doctrine of utility and the concept of public need neither overcome the ethical issues nor substitute for legal sanction.

Lowe, Alexander & Mishkin, *Nontherapeutic Research on Children: An Ethical Dilemma*, 84 J. PED. 468, 469 (1974).

5. *Id.* For the most part, this article addresses only the first of these questions.

6. The field of medical research has burgeoned at an astounding rate since World War II. One key impetus to that growth is the increasing expenditure of federal monies to support clinical investigation. Ratnoff & Smith, *Human Laboratory Animals: Martyrs for Medicine*, 36 FORDHAM L. REV. 673, 675 (1968). Between 1945 and 1965 the yearly expenditures of the National Institutes of Health for medical research and development increased more than 60,000%. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354, 1355 (1966). This sum redoubled between 1965 and 1972, with a national total of 3.3 billion dollars from all sources expended for medical research and development in 1972 alone. DIVISION OF RESEARCH GRANTS, NATIONAL INSTITUTE OF HEALTH, BASIC DATA RELATING TO THE NATIONAL INSTITUTES OF HEALTH 6-7 (1972). No doubt the growth has also been aided by increased funding of research by private industry, most notably the drug industry which has manufactured and marketed a phenomenal number of new drugs since World War II. Reports of the Federal Trade Commission reveal that the drug industry earmarked 800 million dollars for research and development in 1974 alone. U.S. NEWS & WORLD REPORT, June 24, 1974, at 36.

7. The consequences of such a hands-off attitude toward medical research have been aptly predicted by one writer as follows:

experimentation appears in legal periodicals[8] and few courts have considered the issues it raises.[9]

The cases which have spoken in terms of experimentation are largely irrelevant to the issues surrounding clinical investigation as it is practiced today. They involved gross deviations from accepted methods of treatment for the physical ills of individual patients which constituted nothing less than pure quackery. In *Carpenter v. Blake*,[10] for example, the defendant physician set Carpenter's frac-

---

The problem is that if the law does not become involved with scientific advances, and begin to anticipate them and plan for them, scientists and medical investigators will tend to ignore the law during their research phase and make the law *de facto* irrelevant to their discoveries and achievements.

Annas, *Medical Remedies and Human Rights: Why Civil Rights Lawyers Must Become Involved in Medical Decision-Making*, 2 HUMAN RIGHTS 151, 153 (1972).

8. *But see* Kaplan, *Experimentation—An Articulation of a New Myth*, 46 NEB. L. REV. 87 (1967); Ladimer, *Socio-Medico-Legal Aspects of Human Experimentation*, 3 J. PUB. L. 467 (1954); *Medical Progress and the Law*, 32 LAW & CONTEMP. PROB. 561 (1967); Morse, *Legal Implications of Clinical Investigation*, 20 VAND. L. REV. 747 (1967) [hereinafter cited as Morse]. *Symposium: Psychosurgery*, 54 B.U.L. REV. 215 (1974); *A Symposium: Some Legal Problems in Medical Treatment and Research*, 36 FORD. L. REV. 631 (1968); Comment, *Behavior Modification and Other Legal Imbroglios of Human Experimentation*, 52 J. URBAN L. 155 (1974); Note, *Experimentation on Human Beings*, 20 STAN. L. REV. 99 (1967); Comment, *Non-Therapeutic Medical Research Involving Human Subjects*, 24 SYR. L. REV. 1067 (1973); 20 WAYNE L. REV. 1309 (1974).

9. Undoubtedly, some of the reticence of the law to involve itself with human experimentation is due to the immensity and complexity of the area. In experimentation as in anything else, the conclusions one reaches may, in large part, depend upon how the subject matter is defined for analysis. The term "human experimentation" potentially covers a broad range of activities, with clinical studies of accumulated data, *e.g.*, personal or medical histories, educational and social background, responses to psychological questionnaires at one end of the spectrum, involving no physical invasion of the subject's body. At the other end are grossly invasive surgical procedures and the administration of chemicals. *See* Freund, *Ethical Problems in Human Experimentation*, 273 NEW ENG. J. MED. 687, 689 (1965). Whether or not a particular activity constitutes an experiment could also be made to depend on the primary purpose for which it is undertaken. D. MEYERS, THE HUMAN BODY AND THE LAW 71 (1970). Since this article approaches consent for experimentation in terms of benefit to the individual, the term "experimentation" as used herein embraces all attempts to induce, alter or monitor bodily or mental functions where the activity is not reasonably likely to result in the treatment of a condition from which the subject is suffering. Under this view, experimentation could include, among other things: a) deviations from accepted modes of treatment of a specific illness; b) attempts at therapy for conditions for which there is no accepted mode of treatment; c) the use of drugs and other procedures, not for immediate therapy, but for the improvement of sufferers of a specific condition who may or may not include the subject of the experiment; d) the use of healthy persons as subjects or unhealthy persons whose ailment is irrelevant to the goals of the particular activity. *Id.* To this list formulated by Meyers, I would add e) the use of drugs and other procedures in attempts to "treat" persons allegedly suffering from mental "illnesses." *See* text accompanying notes 53-57 *infra*.

10. 60 Barb. 488 (N.Y. Sup. Ct. 1871), *rev'd on other grounds*, 50 N.Y. 696 (1872).

tured elbow using a new and questionable procedure. In addition to holding that a doctor must use modes of treatment which comport with accepted and established medical procedures, the court blanketly warned that the physician who experiments does so at his peril.[11] This strict liability view of experimentation was tempered in 1935 by *Fortner v. Koch*,[12] currently regarded as the seminal case in the area of human experimentation. In much-quoted dicta, the Michigan Supreme Court stated:

> We recognize the fact that, if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient . . . and must not vary too radically from the accepted method of procedure.[13]

In *Fortner*, the defendant physician had employed a novel method of diagnosis and treatment for what was later found to be syphillis, despite the fact that a proven diagnostic technique (Wasserman test) was available. Like *Carpenter*, the case involved actions bordering on quackery by an individual doctor during the course of treating a single patient's physical ailment.[14] The Michigan court seemed to go no further than to impose a standard of reasonableness upon doctors who deviate from accepted treatment techniques.[15]

---

11. *Id.* at 514. In a similar case, Slater v. Baker, 95 Eng. Rep. 860 (K.B. 1767), the defendants, who used a novel procedure and instrument in an attempt to straighten a poorly-mending broken leg, were held liable to the plaintiff, with the court noting that they were unwise in their choice of the experimental device. *Id.* at 862. The "physician's peril" doctrine announced in *Carpenter* was echoed by the court in Owens v. McCleary, 313 Mo. 213, 281 S.W. 681 (1926):

> A failure to employ the methods followed or approved by his school of practice evidences either ignorance or experimentation on his part. The law tolerates neither.

Id. at 685.

12. 272 Mich. 273, 261 N.W. 762 (1935).

13. *Id.* at 282, 261 N.W. at 765. These words have been interpreted both as encouragement of and as a limit on medical experimentation, depending on the writer's perspective. *See* Curran, *Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies*, in EXPERIMENTATION WITH HUMAN SUBJECTS 402 (P. Freund ed. 1970); Morse, *supra* note 8, at 759.

14. *See also* Kershaw v. Tilbury, 214 Cal. 679, 8 P.2d 109 (1932); Graham v. Dr. Pratt Institute, 163 Ill. App. 91 (1911).

15. This approach has been followed by other courts since *Fortner*. *See, e.g.*, Board of Med. Registration & Examination v. Kaadt, 225 Ind. 625, 76 N.E.2d 669 (1948). *See also* Jackson v. Burnham, 20 Colo. 532, 535, 39 P. 577, 580 (1895) (a physician who employs a

To date, *Kaimowitz v. Department of Mental Health*[16] is the first, but certainly not the last,[17] case in which a court has been faced squarely with a situation involving clinical research. The proposed subject, an inmate at state mental institutions for over 15 years, signed a consent form authorizing doctors to implant electrodes in his brain and then perform psychosurgery (selective destruction of brain tissue) in an attempt to "cure" him of allegedly aggressive behavior.[18] The court, after finding that the proposed procedure was experimental, held that the subject could not give informed consent to the psychosurgery.[19]

The focus of the *Kaimowitz* court on consent is, in large part, a result of its adoption of the Nuremberg Code.[20] These ten principles, contained in the final judgment of one of the war-crime trials, represent one of the many sets of ethical codes intended to guide those conducting research on humans.[21] As litigation in the area of medi-

---

method of treatment other than one already established has the burden to "justify his experiment by some reasonable theory"). It should be noted that these early "experimentation" cases are largely after-the-fact damage actions based on negligence theories. It has been suggested that this method of recovery in tort for damages caused may alone be insufficient to compensate subjects of experimentation, giving the burden imposed on the plaintiff to prove deviation from the standard of accepted medical practice in carrying out the experiment. *See, e.g.*, Comment, *Medical Experiment Insurance*, 70 COLUM. L. REV. 965 (1970); Note, *Experimentation on Human Beings*, 20 STAN. L. REV. 99, 113 (1967); Comment, *Non-Therapeutic Research Involving Human Subjects*, 24 SYR. L. REV. 1067, 1091 (1973).

16. Civil No. 19,434-AW (Cir. Ct. Wayne Co., Mich., July 10, 1973).

17. *See* Clay v. Martin, 509 F.2d 109 (2d Cir. 1975); Mackey v. Procunier, 477 F.2d 877 (9th Cir. 1973). Both cases reversed dismissals of complaints by prisoners concerning their inclusion in drug experiments, allegedly without their informed consent.

18. The court rejected the argument of the defendant physicians that the proposed surgery was a form of therapy, largely because of the lack of knowledge about the relationship between behavior and certain brain components, and because of the lack of any demonstrable medical benefit which would accrue to the subject.

19. Kaimowitz v. Department of Mental Health, Civil No. 19,434-AW, slip. op. at 27-29 (Cir. Ct. Wayne Co., Mich., July 10, 1973). That conclusion was based on the lack of voluntariness (because of the inherently coercive institutional environment) and the lack of knowledge about the procedure's effects and risks. *See Symposium: Psychosurgery*, 54 B.U.L. REV. 215 (1974); 20 WAYNE L. REV. 1309 (1974). The doctrine of informed consent was used by the court as the touchstone in the experimental situation to flatly prohibit the class of institutionalized persons from being contemplated as potential "volunteers' for psychosurgery.

20. *United States v. Karl Brandt, Trials of War Criminals Before the Nuremberg Military Tribunals*, 2 THE MEDICAL CASE 181 (1948).

21. Other examples of professional codes include the American Medical Association's *Ethical Guidelines for Clinical Investigation*, OPINIONS AND REPORTS OF THE JUDICIAL COUNCIL 9-11 (1969); the American Psychological Association's *Ethical Standards of Psychologists*, 18 AM. PSYCHOL. 56 (1963); and the World Medical Association's *Declaration of Helsinki*, reprinted in 271 NEW ENG. J. MED. 473 (1964). *See* text accompanying notes 26-38 *infra*.

cal experimentation increases, courts, given the sparse common law guides, may feel constrained to turn to these codes in their efforts to sort out the applicable legal issues and standards.

With regard to children as experimental subjects, a literal reading of the first principle of the Nuremberg Code appears to preclude the use of any minor in medical experimentation since, in most jurisdictions, they lack legal capacity to give consent.[22] The first principle reads in part:

> The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.[23]

Even if minors were made legally capable of giving consent, the question in each case would remain as to whether the child proposed as an experimental subject has "sufficient knowledge and comprehension . . . as to enable him to make an understanding and enlightened decision."[24]

Despite the fact that the text of the Nuremberg Code does not affirmatively allow for proxy consent by a legal guardian on behalf of a ward, the principal drafters of the Code have maintained that third-party consent was not meant to be proscribed by the first principle. Andrew Ivy, Chief Medical Consultant to the War Crimes Trials at Nuremberg, wrote in 1948, the same year the Code was published:

> The ethical principles involved in the use of the mentally incompetent are the same as for mentally competent persons. The only difference involves the matter of consent. Since mental cases are likened to children in an ethical and legal sense, the consent of the guardian is required.[25]

---

22. H. BEECHER, RESEARCH AND THE INDIVIDUAL 231 (1970); Fletcher, *supra* note 3, at 638.

23. *United States v. Karl Brandt, Trials of War Criminals Before the Nuremberg Military Tribunals*, 2 THE MEDICAL CASE 181 (1948), reprinted in J. KATZ, EXPERIMENTATION WITH HUMAN BEINGS 305 (1972).

24. *Id. See* Curran & Beecher, *Experimentation in Children*, 210 J.A.M.A. 77, 80 (1969).

25. Ivy, *The History of the Use of Human Subjects in Medical Experimentation*, 108

The ambiguity in the Nuremberg Code vis à vis children is not present in the other major code of medical ethics, the World Medical Association's Declaration of Helsinki.[26] Section III, 3b of that code declares, much like the Nuremberg Code, that: "The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice."[27]

However, a prior section (3a), in clear contradiction, sanctions proxy consent in some situations by stating that:

> Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured.[28]

Experimentation on children is, therefore, apparently approved of by these guidelines, if the consent of the subject's legal guardian is obtained. Unsurprisingly, the professional codes place no real limits on the power of researchers to select which children will be used as subjects, or for what purposes and in what manner the informed consent of legal guardians will be procured.[29] None of these profes-

---

SCIENCE 1 (1948). *See also* Alexander, *Psychiatry: Methods and Processes for Investigation of Drugs*, 169 ANNALS N.Y. ACAD. OF SCIENCE 347 (1970).

26. Reprinted in 271 NEW ENG. J. MED. 473 (1964).

27. *Id.* at 474.

28. *Id.*

29. The inadequacies of present forms of professional self-regulation have been succinctly described by Professor Jay Katz as follows:

> I am not unduly impressed by the assertion that this research [at Willowbrook State Hospital] was carried out in fidelity to codes of ethics or with the approval of review committees. As I have said elsewhere, codes, as long as they stand alone and are not surrounded by detailed commentary, remain pious exercises of limited value. Since they aspire to ideals and are divorced from the realities of human capacities, e.g., to communicate, to comprehend and to act responsibly, they invite judicious and non-judicious neglect. Similarly, since members of review committees have not given systematic thought to the problems raised by investigative medicine, their approval of research projects often turns out to be as questionable as the activities of individual investigators acting on their own.

PROCEEDINGS OF THE SYMPOSIUM ON ETHICAL ISSUES IN HUMAN EXPERIMENTATION—THE CASE OF WILLOWBROOK STATE HOSPITAL RESEARCH 33 (1972).

Nor, presumably, were the various codes ever intended to place any real restrictions on the researcher's power within the experimental situation. Both the drafters and the endorsers clearly perceive clinical investigation as one facet of the usual doctor/patient relationship, one which has traditionally been free from any outside control. The obvious reason for this "in-house" approach has been understated as follows:

> It is significant that none of the declarations speak to any form of control by groups other than doctors or scientists. The possibility that lay control may be imposed upon

sional codes of ethics have the force of law. Consequently, legal authority for the inclusion of minors in experimentation must be sought elsewhere.

Under the common law, consent is a valid defense to an action for the tort of battery. In the traditional doctor-patient relationship, a "touching" by a doctor in the form of administering medical treatment may be done only with prior consent.[30] The requirement of the consent of the individual is dispensed with only in a few limited situations. One of these is where the person to be touched is legally incompetent to give valid consent. This latter category includes children, for whom the substituted consent of the parent or guardian (not that of the person to be treated) is required in order to avoid tort liability.[31]

---

medical research workers could cause much apprehension to physicians.
Ratnoff & Smith, *Human Laboratory Animals: Martyrs for Medicine*, 36 FORDHAM L. REV. 673, 682 (1968).

The self-serving assumption that the medical experimentation situation is equitable with the normal medical treatment situation conveniently obfuscates the very real differences between the doctor/patient and researcher/subject relationships, including the vastly different goals, motivations and influences at work in each. *See* Guttentag, *The Problem of Experimentation on Human Beings: The Physician's Point of View*, 117 SCIENCE 207, 210 (1953). One writer has stressed that the traditional deference paid the doctor/patient relationship has no place in the experimental setting:

> The responsibility of the individual to an individual patient has been clearly defined, maturely considered, and almost universally accepted; it has been tried and found good. Deliberate experimentation would seem to introduce a break with the accepted type and a replacement by so-called responsibility, which should be deeply and rightly distrusted—the sort of thing that is called the duty of scientific man to society and the obligation of individuals to the race, under which all sorts of monstrosities have been practiced in absolutist states.

Shimkin, *The Problem of Experimentation on Human Beings: The Research Worker's Point of View*, 117 SCIENCE 205 (1953).

30. *See generally* 1 F. HARPER & F. JAMES, THE LAW OF TORTS (1956); W. PROSSER, HANDBOOK OF THE LAW OF TORTS (4th ed. 1971). To be valid, the consent given must meet the requirements of informed consent, *i.e.*, the consent must be knowing and voluntary and the person must be capable of giving the consent. Zoski v. Gaines, 271 Mich. 1, 260 N.W. 99 (1935); Kaimowitz v. Department of Mental Health, Civil No. 19,434 (Cir. Ct. Wayne Co., Mich., July 10, 1973); *see* Ingelfinger, *Informed (But Uneducated) Consent*, 287 NEW ENG. J. MED. 465 (1972); Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW. U.L. REV. 628 (1970).

31. Zoski v. Gaines, 271 Mich. 1, 260 N.W. 99 (1935) (liability for performing tonsillectomy on minor without parental consent); Rogers v. Sells, 178 Okla. 103, 61 P.2d 1018 (1936) (defendant liable in battery for amputating foot of 14 year old accident victim without parental consent). In some jurisdictions, exceptions to this rule have been carved out where the person, even though a minor, was deemed mature enough to understand the consequences of her actions and did, in fact, give consent to the medical treatment. Bakker v. Welsh, 144

The existing case law adopting proxy consent on behalf of minors, however, is limited to instances in which valid consent was (or was not) obtained for customary medical treatment—a procedure undertaken as therapy for a specific physical ailment. To date, no court has directly spoken to the issue of whether a parent has the legal authority to independently consent to any procedure which is not for the minor's medical benefit, *i.e.*, a physical touching involving a minor which is not reasonably intended or expected to cure or ameliorate a physical illness.[32]

The case most often cited by proponents of medical experimentation on minors as legal authority to experiment with parental consent is *Bonner v. Moran*.[33] In *Bonner*, a fifteen year old consented to be a donor of skin for grafts onto his severely burned cousin without his parent's consent. In a subsequent action for assault and battery, the lower court instructed the jury that their verdict must be for the defendant doctor if the minor was capable of consenting to the operation and did so consent. A judgment for the defendant was reversed by the court of appeals which held that the consent of the parent was also necessary.[34] The court placed strong emphasis on the fact the procedures to which the minor in *Bonner* was subjected were not for his personal medical benefit.[35] This point has been stressed by William Curran and Henry Beecher, who argue that *Bonner* thereby implicitly recognizes that minors may be subjected to physical interventions not for their benefit as long as parental consent is obtained.[36] Such broad interpretation of the case appears to be a gross overreading. The narrow holding of the court is a far cry from explicit authorization to parents to independently

Mich. 632, 108 N.W. 94 (1906) (17 year old validly consented to surgery for removal of ear tumor); Gulf & S.I.R.R. v. Sullivan, 155 Miss. 1, 119 So. 501 (1928) (no liability for injuries to arm from vaccination to which mature 17 year old consented); Lacey v. Laird, 166 Ohio St. 12, 139 N.E.2d 25 (1956) (18 year old gave valid consent to plastic surgery).

32. *But see* the transplantation cases cited in note 46 *infra*, in which a non-beneficial physical intrusion was allowed with parental consent, the consent of the child-donor *and* with prior court scrutiny. A benefit analysis was purportedly used, but interpreted broadly so that the avoidance of possible psychological trauma was sufficient "benefit" to the minor donor.

33. 126 F.2d 121 (D.C. Cir. 1941).

34. *Id.* at 122.

35. *Id.* at 123.

36. Curran & Beecher, *Experimentation in Children*, 210 J.A.M.A. 77, 79 (1969). *See also Consent of Minors to Medical Treatment*, in A REVIEW OF LEGAL PRECEDENTS AND MEDICAL ETHICS INVOLVED IN INTERVENTION WITH CHILDREN AT RISK FOR SCHIZOPHRENIA (Appendix III) 13 (1973).

volunteer their children for non-beneficial physical intrusions.[37]

Such a reading is also contrary to the notion of physical inviolability which underlies the law[38] and is reflected by the careful restriction of proxy consent to a physical invasion in cases involving necessary medical treatment. The allowance of third party consent must be based on the requirement that the person giving consent do so on behalf of the ward, solely motivated by the person's best interests.[39] This means that a legal guardian should not be able to consent to a physical touching which is not necessary for the benefit of the child. Consequently, only physical interventions necessary for the improvement of a child's health lie within the scope of authority of parents and legal guardians.[40]

---

37. *See* Capron, *Legal Considerations Affecting Clinical Pharmacological Studies in Children*, 21 CLINICAL RESEARCH 141 (1973).

38. As Justice Cardozo articulated in Schloendorff v. Society of N.Y. Hosps., 211 N.Y. 125, 126, 105 N.E. 92, 93 (1914), "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."

39. Morse, *supra* note 8, at 755; Comment, *Non-Therapeutic Research Involving Human Subjects*, 24 SYR. L. REV. 1067, 1075 (1973).

40. One writer has suggested that this line of reasoning underlies the preclusion of proxy consent in *Kaimowitz*:

> [I]f *Kaimowitz* is suggesting that experimental psychosurgery is a no-benefit, high-risk procedure to which patients should not be induced to submit, the preclusion of guardian consent would follow from the proposition that guardians may not subject their wards to harmful or non-therapeutic experimentation.

Wexler, *Mental Health Law and the Movement Toward Voluntary Treatment*, 62 CALIF. L. REV. 671, 681 n.33 (1974).

The present lack of legal authority for parents to consent to non-beneficial intrusions has been recognized by several experts in the area, including Donald Chalkley of the National Institute of Mental Health:

> A parent has no legal right to give consent for the involvement of his child in an activity not for the benefit of that child. No legal guardian, no person standing in *loco parentis* has that right. Unfortunately, investigators not knowledgeable of the law have asked for consent and parents, legal guardians and institutional superintendents have been giving it, even when the activities were not intended solely to benefit the child.

Chalkley, *Developing Guidelines*, 21 CLINICAL RESEARCH 777, 779 (1973). The same conclusion was reached by the Department of Health, Education and Welfare in its proposed regulations for the protection of human subjects in federally funded research:

> Parents and legal guardians have authority to consent on behalf of their child or ward to established therapeutic procedures when the child is suffering from an illness, even though the treatment might involve some risk.
>
> There is no firm legal basis, however, for parental or guardian consent to participation in research on behalf of subjects who are incompetent, by virtue of age or mental state, to understand the information provided and to formulate the judgments on which valid consent must depend.

38 Fed. Reg. 31,738-39 (1973). *See also* Marston, *Medical Science, the Clinical Trial and*

This "benefit" approach, although not without its own problems, appears to be the one most consonant with the common law protection of a persons bodily integrity. It forms the basis for the currently pending case of *Neilsen v. Board of Regents*,[41] one of the first cases[42] in which a court has been called upon to rule directly on the issue of parental consent to physical intrusions on minors which are not for their direct medical benefit.[43] In *Neilsen*, the plaintiff is seeking to bar the use of normal, healthy infants (ages 2 months to 4 years) as controls in a childhood asthma research study. Blood samples were to be drawn, and several drugs injected, to test the children's tolerance to various substances and stresses. The parents had signed consent forms and were to be paid $300 for a child's participation. The suit itself is not based on any *lack* of informed consent on the part of the parents; indeed, the parents of these minors are named defendants. The *Neilsen* plaintiff alleges that parents have no right to authorize medical intrusions unrelated to improving the physical well-being of their child.

The facts in *Neilsen* demonstrate a clear case of non-therapeutic research.[44] If the "benefit" analysis of proxy consent is adhered to,

---

Society, HOSPITAL TRIBUNE, Jan. 9, 1973, at 14; Hillman & Falk, *Proposed Rules Set Guidelines for Clinical Research on Humans*, 227 J.A.M.A. 13, 14 (1974); *Human Experimentation*, MED. WORLD NEWS, June 8, 1973, at 37.

41. Civil No. 665-049 (Super. Ct. San Francisco, Cal., filed Aug. 1973). *See Is Research on Children Illegal?*, MED. WORLD NEWS, Sept. 28, 1973, at 40.

42. The only other suit to do so is presently pending before a court of general jurisdiction in Detroit, Michigan, Jobes v. Department of Mental Health, Civil No. 74-004-130-DC (Cir. Ct. Wayne Co., Mich., filed Jan. 19, 1974). *See* text accompanying notes 50-53 *infra*.

43. The plaintiff's first cause of action alleges that the state defendants are illegally using public funds to perform acts in contravention of CAL. PENAL CODE § 273(a) (West 1970):

> (1) Any person who, under circumstances or conditions likely to produce great bodily harm or death, willfully causes or permits any child to suffer, or inflicts thereon unjustifiable physical pain or mental suffering, or having the care or custody of any child, willfully causes or permits such child to be placed in such situation that its person or health is endangered, is punishable by imprisonment in the county jail not exceeding 1 year, or in the state prison for not less than 1 year nor more than 10 years.
>
> (2) Any person, who under circumstances or conditions other than those likely to produce great bodily harm or death, willfully causes or permits any child to suffer, or inflicts thereon unjustifiable physical pain or mental suffering, or having the care or custody of any child, willfully causes or permits the person or health of such child to be injured, or willfully causes or permits such child to be placed in such situation that its person or health may be endangered, is guilty of a misdemeanor.

44. The term "nontherapeutic research" denotes that the subject is not reasonably expected to gain medical benefits as an immediate result of the study. Ratnoff & Smith, *Human Laboratory Animals: Martyrs for Medicine*, 36 FORDHAM L. REV. 673 (1968); Comment, *Non-Therapeutic Research Involving Human Subjects*, 24 SYR. L. REV. 1067 (1973). For purposes

the plaintiff in *Neilsen* should prevail, with the court holding directly that parents have no legal authority to consent to procedures on minors which are not for their direct benefit, thereby precluding all non-therapeutic research on minors.[45]

If this focus on the benefit to the child as the determining factor is adopted by the courts, as I believe it should be, it must not be subverted by expanding notions of what constitutes a benefit to the child.[46] Under a strict interpretation of benefit, altruism or avoidance of possible psychological harm should not qualify.[47] This would clearly preclude research such as the now infamous study at the Willowbrook School for the Retarded in which mentally retarded children were given hepatitis with the hope that the research would eventually lead to an effective vaccine.[48] Such studies cannot legally be justified on the basis of any "indirect" benefit to accrue to the children involved or a direct benefit to society as a whole.[49]

---

of this paper, nontherapeutic research is interchangeable with the term experimentation. *See* note 9 *supra*.

45. *See* note 40 *supra*.

46. Daube, *Transplantation—Acceptability of Procedures and the Required Legal Sanctions*, in ETHICS IN MEDICAL PROGRESS—WITH SPECIAL REFERENCE TO TRANSPLANTATION 198 (1966). Such a perversion of the benefit analysis has already occurred in several cases involving minors as donors of organs to siblings. Thus lower courts have held that a kidney could be removed from a healthy minor for transplantation to his twin because it was predicted that the failure to do so would result in "grave emotional impact" to the healthy child. Masden v. Harrison, No. 6865 (Eq. Mass. Sup. Jud. Ct., June 12, 1957). *See also* Hart v. Brown, 29 Conn. Super. 368, 289 A.2d 386 (1972); Foster v. Harrison, No. 6874 (Eq. Mass. Sup. Jud. Ct., Nov. 20, 1957). *Contra*, *In re* Richardson, No. 6091 (La. Cir. Ct. App., Oct. 22, 1973). In *Richardson*, the court held that a parent could not validly consent to the removal of a kidney from one child for transplantation to his ailing sibling. Using the rationale underlying a state law which prohibited parents from disposing of their child's property, the court concluded:

> Since the law affords this unqualified protection against intrusion into a comparatively mere property right, it is incomprehensible to us that it affords less protection to a minor's right to be free from bodily intrusion to the extent of loss of an organ unless such loss be in the best interest of the minor.

Id. slip op. at 5.

47. *Contra*, Skegg, *Consent to Medical Procedures on Minors*, 36 MODERN L. REV. 370, 377-80 (1973).

48. For a sampling of the various views regarding the ethics of the Willowbrook experimentation see H. BEECHER, RESEARCH AND THE INDIVIDUAL 67, 122-27 (1970); Lasagna, *Special Subjects in Human Experimentation*, 98 DAEDALUS 449, 458 (1969); PROCEEDINGS OF THE SYMPOSIUM ON ETHICAL ISSUES IN HUMAN EXPERIMENTATION, THE CASE OF WILLOWBROOK STATE HOSPITAL RESEARCH (1972).

49. The complaint in Nielsen v. Board of Regents, Civil No. 665-049 (Super. Ct. San Francisco, Cal., filed Aug. 1973) is glaringly inconsistent in this respect. It is critical to note that the plaintiff in *Nielsen* is *not* objecting to the inclusion of the non-control children in

Experimentation on minors institutionalized in state mental health facilities is presently being challenged in Michigan in the case of *Jobes v. Department of Mental Health*.[50] The plaintiffs, two minors incarcerated at Lafayette Clinic in Detroit, allege that there is no legal authority for proxy consent to their subjection to medical

---

the proposed allergy study. *See* text accompanying notes 41-42 *supra*. The latter group includes children who are classified as "at-risk" of becoming asthmatics, based on their family medical histories. *Nielsen* implicitly presumes that, because of this factor, their parents do have a right to consent to their subjection to the same risks, pain, fright and physical intrusions proposed for the "healthy" controls. Designation of one group of the children as potentially sick does not alter the fact that the research is clearly not going to result, nor is it designed to result, in any direct medical benefit to the "at-risk" children or to the controls. The study might admittedly produce findings which would ultimately aid asthma sufferers, but it is clearly nontherapeutic research as to both classes of children. Parental consent, then, is no more valid for the non-control children than for the others; all are being used as guinea pigs for someone else's advantage—their parents', asthmatic children's, and the researchers' perhaps, but decidedly not for their own benefit. Jobes v. Department of Mental Health, Civil No. 74-004-130-DC (Cir. Ct. Wayne Co., Mich., filed Jan. 19, 1974). The exact extent to which institutionalized minors are used as subjects in nontherapeutic research is unknown. The Children's Defense Fund of the Washington Research Project is currently compiling an extensive report on experimentation on children, in part using data made available by the federal government which funds much of the research. *See* note 6 *supra*.

Independent investigation in Michigan by myself and a colleague has revealed that from 1970-73 minors incarcerated in various state mental institutions were repeatedly used as subjects in tests of numerous experimental vaccines, including those for mumps, rubella, hepatitis, influenza and parainfluenza.

It would not be surprising to find that Michigan's institutions are not unique in this respect. The reasons why captive populations are favorite targets for investigative medicine are not difficult to discern. Incarcerated people are a self-contained, easily accessible group; they can be monitored on a 24 hour basis over long periods of time frequently required by clinical investigation; they live in stable environments in which such factors as sleep, diet, exercise and social interaction can be easily altered by their institutional custodians; their availability can be used to attract researchers, research money and drug manufacturers into understaffed and underfinanced state facilities. "In short, they represent what the investigator likes to have in his animal rooms and he is reasonably sure the animals will be there for some time." Ritts, *A Physician's View of Informed Consent in Human Experimentation*, 36 FORDHAM L. REV. 631, 637 (1968).

Incarcerated individuals are most likely to bear the brunt of the risks involved in clinical investigation. Not surprisingly, the poor, the deviant and the mentally defective make up the bulk of captive populations. *See* Horstman, *Drug Experimentation and the Poor*, 4 CLEARINGHOUSE REV. 347 (1970). The allowance of nontherapeutic research, such as tests of new drugs and vaccines on institutionalized persons, typifies what I call the doctrine of expendability, referred to as the doctrine of utility by Lowe, Alexander & Mishkin, *Nontherapeutic Research on Children: An Ethical Dilemma*, 84 J. PED. 468 (1974). The insidious attitude underlying these doctrines views these disadvantaged groups as marginal members of society who somehow owe it to the rest of us to make a worthwhile contribution. *See* Ritts, *supra* at 637.

50. Civil No. 74-004-130-DC (Cir. Ct. Wayne Co., Mich., filed Jan. 19, 1974).

experimentation,[51] and that they themselves are incapable of giving informed consent to the procedures because of the inherently coercive institutional environment in which it is being requested.[52]

The children in *Jobes* clearly would not receive any direct medical

51. The two particular experiments proposed at Lafayette Clinic included one study of the effects of administering zinc on the growth patterns of the children. The other experiment was designed to test a hypothesized link between mental illness and the level of bufotenin in the urine of the minors who were institutionalized for alleged emotional disturbances. Plaintiffs' Amended Complaint, Appendix Item H, Research Protocols. Jobes v. Department of Mental Health, Civil No. 74-004-130-DC (Cir. Ct. Wayne Co., Mich., filed Jan. 19, 1974). Bufotenin levels have previously been the subject of clinical investigation employing adults labelled as schizophrenics. *See, e.g.*, Narasimhachari & Himwich, *The Determination of Bufotenin in Urine of Schizophrenic Patients and Normal Controls*, 9 J. PSYCHIAT. RESEARCH 113 (1972); Siriex & Marini, *Studies on the Elimination of Bufotenin in Urine*, 1 BEHAV. NEUROPSYCH. 29 (1969). Both studies are clearly nontherapeutic since the subjects are not to gain from them any medical benefit in the form of improving a condition from which they are suffering and which necessitates medical attention. The first of the experiments readily demonstrates the proclivity of clinical investigators to make use of institutionalized persons, simply because they are accessible. *See* note 49 *supra*. The second demonstrates the ease with which researchers can conduct experiments on persons once they are labelled as being "sick," if the experiment is performed under the free-flowing rubric of "treatment." *See* note 18 *supra* and text accompanying notes 53-57 *infra*.

52. This argument draws on the reasoning of the court in *Kaimowitz*. *See* text accompanying notes 16-19 *supra*. The plaintiffs also claim that the state defendants are acting in violation of the constitutional rights of the children under the fourteenth amendment, alleging that they are being deprived of their rights to liberty and privacy. Plaintiffs' Amended Complaint at 11-12, Jobes v. Department of Mental Health, Civil No. 74-004-130-DC (Cir. Ct. Wayne Co., Mich., filed Jan. 19, 1974). *See* Romano, *Reflections on Informed Consent*, 30 ARCH. GEN. PSYCHIAT. 129, 132 (1974) [hereinafter cited as Romano]. *See also* Relf v. Weinberger, 372 F. Supp. 1196 (D.D.C. 1974). On the day of the first hearing in *Jobes*, the state attorney general sent a letter to the Director of the Department of Mental Health advising him that:

> The Department may not conduct experiments on [committed minors] unless the particular experiment contributes directly to the individual minor's care and treatment.

Letter from Frank J. Kelley to E. G. Yudashkin, Feb. 19, 1974. Furthermore, the attorney general cautioned that the decision in *Kaimowitz* would indicate that the children themselves could not consent because of the "coercive atmosphere of a mental institution," and added:

> While it is true that a parent can consent on behalf of a child to medical procedures which are necessary to preserve the health of the child, *e.g.*, Bakker v. Welsh, 144 Mich. 632 (1906), nationally, cases have held that this does not empower the parent to make his child a guinea pig. The parent has no authority to subject his child to medical procedures which are not designed primarily for the benefit of that child.

Id.

During the early stages of the litigation in *Jobes*, the plaintiffs and the state defendants agreed to a consent order which would have prohibited experimentation on institutionalized minors. The order, however, was never entered by the court due to the opposition of intervening defendants in the case, including the Michigan Association for Emotionally Disturbed Children.

benefit from the proposed procedures.[53] Besides the absence of any benefit to them, there is also considerable doubt as to whether there is a condition requiring any medical intrusions. *Jobes* directly raises the question of what is treatment. But more importantly, it questions whether there is anything to treat in the first place—*i.e.*, whether being labelled as mentally ill or emotionally disturbed justifies the application of any medically intrusive procedure, usually the administration of drugs.

One concomitant to the tort principle which permits proxy consent for accepted medical treatment[54] is the requirement that there be a condition which necessitates a touching of the person in the form of some attempt at treatment. In psychiatry, the existence of a "disease" requiring treatment is, at best, questionable. The "treatment" for an alleged mental illness may involve chemotherapy, electroshock, or surgery on the brain.[55] Whether the application of any of these techniques results in a medical benefit to a particular recipient is rightly a subject for large doses of skepticism, given the nebulous and value-laden nature of psychiatry itself.[56] The requirement of direct benefit to a child before proxy consent to a physical intrusion is valid cannot be deemed to be satisfied by a mere assertion that a child is mentally ill or emotionally disturbed.[57]

---

53. Not only does inclusion in the bufotenin study result in violation of the bodily integrity of the children and no direct medical benefit to the children, but it can lead to mislabelling by researchers which has serious social and legal consequences. *See generally* ISSUES IN THE CLASSIFICATION OF CHILDREN (N. Hobbs ed. 1975).

54. *See* text accompanying notes 30-32 *supra*.

55. *See* Kaimowitz v. Department of Mental Health, Civil No. 19,434-AW (Cir. Ct. Wayne Co., Mich., July 10, 1973). *See also* Note, *Conditioning and Other Technologies Used to "Treat?" "Rehabilitate?" "Demolish?" Prisoners and Mental Patients*, 45 S. CAL. L. REV. 616 (1972).

56. Perhaps in psychiatry, more than in other branches of medicine, one senses deep concern with matters of personal liberty, civil rights, freedom of the individual to make his choices of health services as well as participating in human experimentation.

Romano, *supra* note 52, at 131.

57. For example, a debate currently rages among medical experts over whether hyperkinesis in children (alternately called hyperactivity or minimal brain dysfunction) is a condition requiring the application of any kind of medical "treatment." Even those who believe that there is such a "disease" decry attempts to "treat" it with drugs. *See* Grinspoon & Singer, *Amphetamines in the Treatment of Hyperkinetic Children*, 43 HARV. ED. REV. 515 (1973); Sroufe & Stewart, *Treating Problem Children with Stimulant Drugs*, 289 NEW ENG. J. MED. 407 (1973); Vonder Harr, *Chaining Children with Chemicals*, THE PROGRESSIVE, March, 1975, at 13. Yet hundreds of thousands of schoolchildren are currently receiving daily doses of stimulant drugs, primarily methylphenidate hydrochloride, in what could be the largest

Focusing on the presence or absence of a direct medical benefit to determine whether there is legal authority for proxy consent to any physical touching raises some tough problems of line-drawing. The most difficult of these would arise in the traditional doctor/patient situation where a physician attempts to treat a physical ailment with unproven measures. Where established methods of treatment are already available and are not medically contraindicated, there is no reason why the child patient should not have the benefits of those established therapies. When their use proves ineffective (or when no accepted mode of treatment exists), unproven techniques may be called for. But even within the normal setting of the doctor/patient relationship, some attempts at "therapy" cannot reasonably be expected to result in a direct medical benefit to a child in the form of improvement in her condition. At some point, then, the possibility of effectiveness becomes so remote that no benefit can be said to be present. The mere existence of a potential benefit cannot in and of itself be used to avoid the strictures of a rule which prohibits proxy consent to a procedure which is not for the direct benefit of the child.

The proposition that proxy consent cannot be obtained for nontherapeutic research on minors no doubt will be viewed with great distaste by those who consider the perceived needs of society as paramount to the rights of particular members of that society.[58] The law, however, has traditionally been acutely sensitive to ensuring that the individual is protected from the whims and impositions of the majority, even those magnanimously couched in terms of sacrifice for the greater good. Tort law, in particular, has consistently

---

nontherapeutic research study ever conducted by the drug industry. Likewise, psychosurgery on children under the protective guise of providing "treatment" for hyperactivity constitutes a gross example of illegal and unjustifiable experimentation. *See* Andy, *Hyperresponsive Syndrome*, in TRANSACTIONS OF THE 2ND INTERNATIONAL CONF. ON PSYCHOSURGERY (1970); Andy, *Thalamotomy in Hyperactive and Aggressive Behavior*, 32 CONFIN. NEUROL. 322 (1970); Balasumbramaniam, *Surgical Treatment of Hyperkinetic and Behavior Disorders*, 54 INT. SURGERY 18 (1970); Breggin, *The Return of Lobotomy and Psychosurgery*, 118 CONG. REC. E1602 (daily ed. Feb. 24, 1972); Restak, *The Promise and Peril of Psychosurgery*, SATURDAY REV., Sept. 25, 1973, at 54.

58. To the inevitable argument that the exclusion of minors as organ donors will greatly hamper medical advancement in the area of transplantation, one writer has responded:

> If this is so, it is regrettable, but medical progress must then be hampered. . . . Anyway, I do not believe that anyone has the right to dispose of an organ simply because this is a child.

Daube, *Transplantation—Acceptability of Procedure and the Required Legal Sanctions*, in ETHICS IN MEDICAL PROGRESS—WITH SPECIAL REFERENCE TO TRANSPLANTATION 199 (1966).

recognized that persons should only endure those bodily intrusions which they have freely chosen. The common law does not inquire as to whether the majority would consent to a similar physical intrusion or as to whether most people think a person should allow the physical touching. Instead, the inquiry is narrowly and appropriately focused on the wishes of the individual. The allowance for proxy consent is a limited exception to that rule. The exception neither negates the principles underlying the law of assault and battery, nor gives free rein to guardians to approve of any and all invasions of the ward's personal integrity. This proposition is not a revoluntary one; it was succintly stated by the Supreme Court of the United States in *Prince v. Massachusetts*[59] as follows:

> Parents may be free to become martyrs themselves. But it does not follow [that] they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.[60]

Likewise, those who are motivated by the desire to serve humanity through the advancement of medicine have no greater rights to determine which individuals shall make the sacrifice.[61] Like it or not, medical investigators must come to recognize that "for the greater good" is just not good enough:

> It is essential that while humanity and science are served, the individual's rights must be protected with vigor and vigilance. If this means that certain experiments cannot be conducted, it is appropriate that they are not. Medical scientists in the laboratory are privileged to embrace an operative pragmatism during the continuum of inductive and deductive reasoning, intuition, imagination and possibly even serendipity that comprise the scientific method. Occasionally, the means and the end are blurred and may even be indistinguishable. In the clinical experiment with human subjects this facile laboratory stratagem cannot be permitted, for here the end can never justify the means if human rights and dignity are violated. There is a special meaning for the scientist in this cliche, for he above all

59. 321 U.S. 158 (1944).

60. *Id.* at 170.

61. Whoever gave the investigator the god-like right of choosing martyrs?" Beecher, *Consent in Clinical Experimentation: Myth and Reality*, 195 J.A.M.A. 34, 35 (1966).

others exalts in his freedom to seek the truth of life and he is first a human, then a scientist.[62]

62. Ritts, *A Physician's View of Informed Consent in Human Experimentation*, 36 FORDHAM L. REV. 631, 638 (1968).